FBI Laboratory
Practices for Authorizing Deviations

1 Purpose

There are times when deviating from FBI Laboratory-issued quality system document requirements is necessary. These practices specify the actions required to request and authorize deviations. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

2 Scope

These practices apply to FBI Laboratory personnel who are involved in requesting and/or authorizing deviations from FBI Laboratory-issued quality system documents.

3 Practices

Deviations must be requested and authorized prior to departing from the specified requirement(s). An authorized deviation does not eliminate the requirement for validating modifications to examination of evidence or DNA databasing procedures.

3.1 Minor Deviations

A minor deviation is not expected to significantly impact the quality system and applies to a single instance or a finite number of instances at the time requested. Minor deviations may not be used if a document is identified as no longer being fit for purpose.

3.1.1 When there is a need for a minor deviation from a specified requirement(s), the approver will consider the merits and risks of a minor deviation before approving a proposed deviation. For minor deviations of an administrative nature, the person's manager or Technical Leader will serve as the approver. For minor deviations of a technical nature, the Technical Leader will serve as the approver. If the Technical Leader requests a minor deviation of a technical nature, another person qualified and authorized in the same discipline and/or category of testing will serve as the approver.

3.1.2 A *Major Deviation Request* (7-258) will not be used for minor deviations. The record of the minor deviation will include:

- The title of the document (or unique identifier), issue date and/or revision number, and the specific requirement(s) from which a minor deviation is sought.
- A statement of the specific deviation.
- The name and initials or signature of the approver and the date of the

authorization or the electronic equivalent if retained in Forensic Advantage (FA).

3.1.3 When the minor deviation is applicable to examinations or DNA databasing, the deviation and its authorization will be included in the FBI Laboratory file (e.g., uploaded to the Case Object Repository, physical copy in the 1A, Case Record Communication Log in FA).

3.1.4 For minor deviations not directly applicable to examinations or DNA databasing, the deviation and its authorization will be maintained by the appropriate unit personnel.

3.1.5 Units, disciplines, and/or categories of testing will record minor deviations in a centralized location (e.g., FA, binder, spreadsheet). Records will include specific information to allow for a unit, discipline, and/or category of testing to determine any trends. Unit Chiefs and Technical Leaders will ensure minor deviation records are reviewed, at a minimum on an annual basis, to determine what, if any, trends are occurring that may require revision to the appropriate document(s). The review of minor deviations will be recorded and will include a notation as to whether any trends were identified. The review of minor deviations will be recorded and will include a notation as to whether any trends were identified.

3.2 Major Deviations

A major deviation has the potential to significantly impact the quality system and/or is expected to affect multiple, unknown number of instances or be applicable over an extended period of time. No major deviation can be implemented until all authorizations are recorded.

3.2.1 Initiating a *Major Deviation Request*

When a major deviation is needed, the requestor will initiate a *Major Deviation Request* in the Deviation Request Database and specify:

- The title (or unique identifier) of the document(s), issue date and/or revision number, and the specific requirement(s) from which a major deviation is sought.
- Description of the requested deviation (i.e., what the deviation will cover).
- The specific instance(s) for which the deviation is requested (i.e., when the deviation will be needed or to which specific circumstance(s) the deviation will apply).
- The reason for the requested deviation (i.e., why the deviation is needed).
- The merits and the risks of the requested deviation.
- The duration of the requested deviation.

3.2.2 Authorization

The requestor of the major deviation will submit the *Major Deviation Request* to the appropriate Unit Chief(s) for authorization. For major deviations of a technical nature the Technical Leader

will also serve as the approver. If the requestor is a Unit Chief or Technical Leader, they will sign the authorization.

3.2.2.1 The Unit Chief(s) and Technical Leader, when applicable, will evaluate the merits and risks of the major deviation. Risks may include contamination, security, defensibility, deleterious change, and/or safety. If they determine the merits of the proposed major deviation outweigh the risks, they will sign the *Major Deviation Request* to record their authorization and forward the request to the Quality Manager.

3.2.2.2 The Quality Manager will evaluate the proposed major deviation regarding good laboratory practice and potential impact on the quality of the work and the quality system. The Quality Manager will determine whether the *Major Deviation Request* impacts the examination or reporting process and needs to be referenced in the FBI Laboratory file. The Quality Manager will record their authorization or rejection on the *Major Deviation Request*. If the Quality Manager authorizes the major deviation, they will sign the *Major Deviation Request* and forward the request to the appropriate Section Chief or Laboratory Director. The Laboratory Director will review a major deviation when it applies to personnel in multiple sections of the FBI Laboratory.

3.2.2.3 The Section Chief or Laboratory Director will review the *Major Deviation Request* and will record their authorization or rejection on the *Major Deviation Request*. The Section Chief or Laboratory Director will sign the *Major Deviation Request* to record their authorization. The Section Chief or Laboratory Director will return the Major Deviation request to the Forensic Analysis Support Unit (FASU), whether it is authorized or rejected.

3.3 Allowable Duration of a Minor or Major Deviation

Authorized minor deviations will be valid for only the specific instance(s). Authorized major deviations will be valid only for a specified time period or circumstance not to exceed six months. The specific duration must be specified on the *Major Deviation Request*.

3.3.1 FASU personnel will record the expiration date following all authorizations.

3.3.2 Major Deviation Renewal

Authorized major deviations may be renewed by the Quality Manager for up to an additional six months. The renewal duration will be specified on the *Major Deviation Request*.

3.4 Authorized Major Deviation Records

The original, physical copy of a *Major Deviation Request* will be retained in the FASU whether it is authorized or rejected. The FASU will post all authorized *Major Deviation Requests* to BUNET and LABNET.

3.4.1 If the Quality Manager determines the *Major Deviation Request* impacts the examination or reporting process, a copy of the authorized *Major Deviation Request* will be included in the FBI Laboratory file for each applicable case (e.g., attach to a communication log entry, upload to the Case Object Repository, physical copy in the 1A). Alternatively, the unique identifier of the *Major Deviation Request* may be recorded on the appropriate communication log (e.g., *Activity and Communication Log* (7-245), Case Communication Log, Case Record Communication Log).

If the Quality Manager determines the *Major Deviation Request* does not impact the examination or reporting process, it is not necessary to include or reference the *Major Deviation Request* in the FBI Laboratory file.

3.5 Major Deviation Notifications

When a major deviation has been authorized, renewed, or inactivated, the Quality Manager will ensure the requestor is notified by email. The requestor will ensure the affected personnel are notified by email. The notifications will be retained.

4 Records

The following records will be generated and/or retained as a result of these practices through at least one accreditation cycle.

- Minor deviations applicable to examinations or DNA databasing will be retained with the FBI Laboratory file.
- Minor deviations not applicable to examinations will be retained according to the retention requirements of the associated record, at a minimum the current accreditation cycle.
- Centralized records of minor deviations.
- Annual review of minor deviations.
- The original of each *Major Deviation Request* will be permanently retained by the FASU.
- A copy of a *Major Deviation Request* will be retained with the FBI Laboratory file for each applicable case or a reference to the unique identifier of the *Major Deviation Request* may be recorded on the appropriate communication log.
- Notifications regarding major deviations.

5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17020 - Conformity Assessment - Requirements for the Operation of Various Types of Bodies Performing Inspection, International Organization for Standardization, Geneva, Switzerland, 2012.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev #	Issue Date	History
7	06/03/19	In sections 3.1.2, 3.1.3, and 3.1.5 added the option to use FA for recording the use of minor and major deviations. Clarified section 3.1.5 regarding minor deviation records and their reviews. In sections 3.2.2.2 and 3.4.1 added requirement for the Quality Manager to determine whether a major deviation impacts the examination or reporting process and must be referenced in the file. Updated list of references in section 5. Revised *Major Deviation Request* in Appendix A.
8	12/21/20	Grammatical and editing changes made throughout for clarity Replaced: casework with examinations throughout Replaced: Deputy Assistant Director with Laboratory Director throughout 3.1.1 – Added: If the Technical Leader requests a minor deviation of a technical nature, another person qualified and authorized in the same discipline and/or category of testing will serve as the approver 3.3.1 – Replaced: A Quality Assurance Specialist with FASU personnel 3.4.1 – Added: for each applicable case 4 – Added: A copy of a *Major Deviation Request* will be retained with the FBI Laboratory file for each applicable case or a reference to the unique identifier of the *Major Deviation Request* may be recorded on the appropriate communication log. 5 – Added: ISO/IEC 17020

Redacted - Signatures on File

Approval

Laboratory Director Date: 12/18/2020

Quality Manager Date: 12/18/2020

Appendix A: *Major Deviation Request* (7-258)

Redacted - Form on File